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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,925	10/15/2003	Dwight L. Anderson	110.01840101	7050

26813 7590 02/07/2006

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	**Application No.** 10/685,925	**Applicant(s)** ANDERSON ET AL.	
	Examiner Zachariah Lucas	**Art Unit** 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/10/05*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-9, and 13-15 are pending in the application.

2. In the prior action, the Allowance mailed on September 21, 2005, claims 1-15 were pending. In that action, claims 1-9 and 13-15 were allowed, and claims 10-12 were cancelled by Examiner's amendment.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 10, 2005 has been entered.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on November 10, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **(New Rejection)** Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Madonna et al. (U.S. 2004/0224359- cited in the November 2005 IDS). These claims read on a method for the detection of a bacterial cell in a sample wherein the method comprises the use of a bacteriophage specific to the target cell, and comprising a binding agent (esp., a biotinylated phage). The claimed method includes the steps of contacting a sample with the biotinylated phage, incubating the sample such that any target cells present are infected and produce progeny phage (which do not comprise the binding agent/biotin), removing the biotinylated parent phage from the sample using a probe comprising a ligand to the binding agent (e.g. streptavidin), and detecting the progeny phage. Such a method is also taught by the Madonna reference. See e.g., pages 1-2, paragraphs [0008] and [0009]; and page 2, paragraphs [0011]-[0014]. Thus, the reference anticipates the indicated claims.

It is noted that the present application claims priority to U.S. provisional application 60/418,822. However, while this provisional application provides descriptive support for two methods of using bacteriophage for the detection of a target bacterium, it does not provide support for the presently claimed methods. As indicated above, the presently claimed method involves the introduction to a sample of a phage comprising a binding agent, wherein the phage is not attached to a probe or other substrate. The present methods also indicate that a probe comprising a ligand to the binding agent is used to remove the phage with a binding agent from the sample after an incubation step in which progeny phage may be produced (if the target bacterium is in the sample).

The '822 application teaches two alternative methods of using a phage to detect a bacterium in a sample. In one case, a phage is immobilized on a substrate which is first brought into contact with the sample, and then removed after the incubation step. See e.g., page 2. In this embodiment, it is noted that the phage may be immobilized to the substrate through the use of biotin and streptavidin. Page 12. However, the teachings of the '822 require that, in this embodiment, the phage is attached to the substrate prior to introduction to the sample.

In the second embodiment described by the '822 application, a parent phage is introduced to the sample, permitted to infect any target cells present, and then the parent phage are removed from the sample before the incubation step in which progeny phage are produced.

Neither of these methods provides support for the presently claimed embodiment. In the first case, although there is a phage comprising a binding agent, the phage in that method must be attached to a substrate, unlike in the present case, wherein the phage with the binding agent are introduced to the sample free of the substrate, and only later captured on the substrate for removal. In the second case, a free (not immobilized) parent phage which is not described as comprising a binding agent is introduced to a sample, but is removed from the sample prior to the production of the progeny phage. Thus, the teachings of the '822 application do not provide support for the presently claimed invention. Because of this, and because the Madonna reference has a filing date prior to the current application, the reference applies as 102(e) against the presently claimed methods.

It is noted that although Madonna claims priority to an earlier provisional application, that provisional application also does not appear to provide support for the presently claimed invention.

6. **(New Rejection)** Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madonna as applied to claims 1-6 above, and further in view of the teachings of Terlesky et al. (U.S. 2004/0152085), Stroobant et al. (U.S. 2002/0090637), and Petersen et al. (U.S. 2002/0042125). These claims identify a number of structures that may be used for the capture of the phage comprising the binding agent in the previously described methods. Although the Madonna reference refers specifically to the use of beads (see e.g., page 2, paragraph [0014]), the reference generally describes the removal of the tagged phage using biotin/streptavidin binding, without limiting the substrate which is used to capture the phage. The substrates listed in the indicated claims represent substrates that are known in the art for use in capture assays. See e.g., Terlesky, page 2 paragraph [0012]; Stroobant, page 3 paragraph [0028]; and Petersen, page 2 paragraph [0018]. Because all of these materials represent substrates known in the art as useful in capture assays, it would have been obvious to those of ordinary skill in the art to use any of them as the substrate for the ligand used to capture the phage with the binding agent. The teachings of these references in combination with the teachings of Madonna therefore render the alternative embodiments of claims 6 and 9 obvious.

7. **(New Rejection)** Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madonna as applied to claims 1-6 above, and further in view of Teodorescu et

al. (U.S. 4,797,363- of record in the April 2004 IDS). Claim 7 further limits the method of claim 1 to embodiments of the method wherein the new bacteriophage are detected through the use of a fluorescent dye or nanocrystal. Claim 8 requires that the detection be made through the use of a light microscope. The teachings of Madonna have been described above. While the reference teaches the use of mass spectrometry for the detection of the progeny phage, the reference also indicates that other detection technologies may also be used. Page 3, paragraph [0028]. However, the reference does not specifically refer to the technologies of claims 7 and 8.

However, the Teodorescu reference teaches the use of phage as identification agents in methods of detecting biological structures. The reference teaches that the presence of bound phage may be visualized through conjugation of the phage to a visualizing agent, which may be a fluorescent dye. Column 3, esp. lines 60-64. The reference teaches that such dyes may be detected through the use of a light microscope. See e.g., Column 9, lines 43-65. Because the reference teaches that the labeling of phage with such dyes allows for their presence to be detected, it would have been apparent to those in the art that such a method of detecting the phage is a functional equivalent of the mass spectrometry method used in Madonna. It would therefore have been obvious to those in the art to substitute the fluorescence-based method of detection for the detection technique used in Madonna. Thus, the combined teachings of these references render obvious the claimed methods of detecting bacterial cells.

8. **(New Rejection)** Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madonna as applied to claims 1-6 above, and further in view of the teachings of Olsvik et al. (Clin Microbiol Rev 7:43-54- of record in the April 2004 IDS) and Yazdankhah

et al. (Vet Microbiol 62:17-26- of record in the April 2004 IDS). These claims describe the method of the claims above, wherein the new bacteriophage are detected by complexing the new phage with a substrate comprising an immobilized binding agent to the new phage, and detecting the phage/substrate complex. The teachings of Madonna have been described above. As was previously indicated above, while the reference teaches the use of mass spectrometry for the detection of the progeny phage, the reference also teaches that alternative detection technologies may be used.

Olsvik teaches a method for the detection and identification of viruses and bacteria comprising their capture on a substrate with a ligand or binding agent thereto. See e.g., page 43. Additionally, the Yazdankhah reference teaches a method for the detection of bacteria through the conjugation of a bead to an antibody, and the use of the conjugated bead/antibody in a sandwich assay for the target bacterium. From these teachings, it would have been obvious to those in the art that the bead/antibody binding agent conjugate could also be adapted to detect phage. As the use of such beads for the detection of phage was known in the art, and would have been recognized as an alternative to the plaque assay for the detection of the new phage, it would have been obvious to those in the art to substitute such a method for the detection of the new phage for the mass spectrometry assay used in the method of Madonna. The teachings of these references therefore render the indicated claims obvious.

Conclusion

9. No claims are allowed.

10. The teachings of the Voorhees et al. (U.S. 2005/0003346) reference cited in the November 2005 IDS are considered redundant to the teachings of the Madonna reference applied above.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 2/6/06
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